- E. Development of novel technologies for in situ remediation of contaminated sediments, soils, and groundwater.
- F. Development of cost-effective devices to detect or remediate chemical mixtures in environmental media.
- G. Development of nano-enabled structures, electrochemical methods, photocatalytic processes, thermal treatments, or filtration-based methods of remediation.
- H. Development of bioremediation and phytoremediation technologies including the use of genetic engineering approaches.

SRP recognizes the important public health impact of detection or remediation technologies that are applicable to non point-source air pollution and drinking water; however, a higher priority will be placed on remediation and detection technologies with a clear connection to sites impacted by hazardous substances.

Improved Test Systems for Prioritization and Safety Evaluation

The NIEHS is interested in: (1) developing, standardizing, and validating sensitive and specific innovative tests and integrated testing strategies that can reduce, refine, or replace animal use and that will provide improved predictivity, and potential cost and time savings compared to current standard laboratory animal tests (i.e., assays for carcinogenicity, immunotoxicity, reproductive or developmental toxicity, dermal toxicity, and neuro or other organ system toxicity including acute local and systemic toxicity); and (2) developing mid- and high-throughput screens and tests using phylogenetically lower animal species (e.g., insects, fish, worms) to evaluate mechanisms of toxicity to identify mechanisms of chemically-induced biological activity, prioritize chemicals for more extensive toxicological evaluation, and develop more predictive models of *in vivo* biological response. The proposed tests and strategies should use computational and/or biochemical models, cell/ tissue cultures, and/or animal models that are relevant to existing safety assessment databases and human experience, and that can be extrapolated to estimate risks to humans. The endpoints for these tests or assays should take advantage of the new technologies such as genomics, transcriptomics, proteomics, and bioinformatics and of novel endpoints (biomarkers) including those that are non-invasive. Examples include but are not limited to:

- A. Biokinetic models that include the integration of toxicodynamic and biokinetic modeling to predict acute and chronic systemic toxicity from *in vitro* data.
- B. *In vitro* test methods and integrated strategies (e.g., undifferentiated/ differentiated human/mammalian stem cell model systems, organotypic model systems, biochemical activity [e.g., peptide binding]; and computational models) that can be used to prioritize compounds for more extensive testing and/or to predict acute and chronic toxicity by taking into account, for example, metabolism, the ability of chemicals to pass through barriers (i.e., blood brain, kidney, lung, gastrointestinal), and organ specific effects, or which allow the development of endpoints that can be extrapolated to *in vivo* biomarkers of toxicity. An emphasis is placed on the development of engineered 3D tissue systems that include multiple cell types and that replicate the anatomy and function of intact tissue. Of particular interest are systems that replicate key functions of major organs (e.g., skin, kidney, lung and the gastro-intestinal track) and the ability to incorporate immunological function in these models. Also important is the ability of such systems to replicate human xenobiotic metabolism.
- C. Alternative assays and integrated strategies to assess dermal irritation, dermal absorption, dermal hypersensitivity phototoxicity, and ocular toxicity.
- D. Non-mammalian or invertebrate models for specific toxicities that utilize endpoint that are conserved across species so the results can be extrapolated to human risk.
- E. Identification and validation of predictive biomarkers that can be used to obtain improved mechanistic information and/or serve as the basis for earlier endpoints in toxicological studies.

- F. Use of formalin fixed, paraffin embedded (FFPE) tissues from animals and/or humans to extract RNA, miRNA or DNA for molecular profiling and toxicity classification of archival samples. Recent technological developments have made extraction of nucleic acids from FFPE tissues more feasible for paraffin archival tissues. There is a need for accelerated throughput methods using extracted RNA, miRNA or DNA (e.g., methylated DNA) from archival paraffin samples to demonstrate the mode of action for chemical toxicity after in vivo exposure or for use in tumor type classification in either clinical samples or animal bioassay studies. Appropriate platforms for genomic-wide studies of FFPE samples would be useful for pathway discovery and mechanistic inquiry. Also the development of platforms that could examine gene signatures for a large number of samples would be helpful for large-scale validation work. Possible technologies include fluorescent oligomers, hybridization-based platforms, or NextGen sequencing
- G. Computational models that use data from *in vivo* and *in vitro* omics studies, *in vitro* mid- and high-throughput assays, and classical animal and human toxicological studies to link chemicals to genes, genes to pathways, and pathways to disease.

Education and Outreach

As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing educational and training resources for students of all ages, educators, health care professionals, and the lay community to enhance their knowledge of environmental health sciences and apply it to their daily lives. These resources are an important part of our strategy that encompasses both communication and capacity building through training, education, and community outreach. Resources may be directed to all levels of education: Kindergarten through 12th grade, undergraduate, graduate, adult education, health care professional training, and community outreach. Products may include:

- A. Mobile and distance strategies. With the proliferation of applications for mobile phone use as well as tablet technologies, NIEHS encourages the development of applications and technology to increase knowledge of environmental health topics and to apply that knowledge to daily living.
- B. Gaming approaches. These can include materials for use within or outside the classroom. The goal is to enable players to develop understanding of environmental health concepts actively, at their own pace and ability.
- C. Television shows. Educational shows with accompanying lessons or activities to enable broader use of the show to increase awareness of environmental health issues.

Resources on subjects of particular interest include education on known or emerging environmental toxicants, risk communication, environmental justice, health disparities, cumulative exposures, windows of susceptibility, and gene-environment interactions.

All educational resources must be aligned with state and federal standards. Training materials and activities for health care professionals should include continuing education units. Small businesses should partner with environmental health scientists, educators, communication researchers, health literacy experts, or training specialists to form research teams with the required expertise to develop technology or products using the best available science in environmental health.

Other Topics Within the Mission of the Institute

For additional information on research topics, contact:

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NATIONAL EYE INSTITUTE (NEI)

The NEI supports research with respect to eye diseases, visual disorders, mechanisms of normal visual function, preservation of sight, and the special health problems and requirements of individuals with impaired vision. Applications for all areas of vision research are encouraged. Examples that may be of interest to small businesses are provided below, but this list is not meant to be exhaustive.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. NEI does not fund Phase I applications greater than \$225,000 total cost per year for up to 1 year or Phase II applications greater than \$750,000 total cost per year for up to 2 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

The NEI will accept Phase IIB SBIR or STTR Competing Renewal grant applications from Phase II SBIR or STTR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage where interest and investment by third parties is more likely. The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR or Phase II (R42) STTR grant. NEI grantees seeking SBIR or STTR Phase IIB Competing Renewal